

01/31/2006

**Remarks/Arguments:**

The Office Action rejects claims 1-19 and 21-39 under U.S.C. § 102(b) as being anticipated by Desai et al. US 5916596. The Office Action also makes multiple rejections under U.S.C. § 103(a). Claims 1-19 and 21-39 [sic. 38] are rejected as being unpatentable over Parikh et al. US 5922355 in view of Chagnon et al US 5389377, and claims 1-7, 11, 21-39 [sic. 38] are rejected as being unpatentable over Desai et al. US 5916596.

Applicants respectfully point out that the previous Amendment erroneously numbered the last claim in this application. The present paper changes claim 39 to claim 38, and hereinafter applicants refer to claim 38 rather than claim 39 (as presented in the Office Action).

Concerning the § 102(b) rejection, the Office suggests that Desai's method of sonicating an emulsion teaches the invention claimed by the applicants. However unlike applicants, Desai does not teach sonication of an emulsion to evaporate a water immiscible organic solvent to cause a pharmaceutically active agent, dissolved in the organic solvent, to precipitate into the aqueous phase and form particles. Instead Desai uses sonication to create: 1) nanodroplets that contain dissolved pharmaceutically active compounds, and 2) a crosslinked biocompatible (e.g. protein) coat that encapsulates the pharmaceutically active compound. Desai's particles are a "shell of crosslinked polymer" formed by high shear conditions that create "superoxide ions that are capable of crosslinking the polymer" (col. 8 lines 35-47). In Desai, after high shear force treatment the polymer contains "small nanodroplets of the nonaqueous solvent (containing the dissolved pharmacologically active agent)." (col. 9 lines 31-35).

Furthermore, Desai does not teach sonication or any other method to cause precipitation of a pharmaceutically active compound to create particles. Instead, Desai teaches that the polymer (protein) coating may contain a liquid or solid pharmaceutically active agent. (col. 7

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